

Submission Management Services



CGI's submission management services are a subset of our regulatory services for supporting life sciences organizations of all sizes.

Our submission management services support clients with:

- A robust global model able to support 24/7 operations if required
- Experts with extensive experience supporting multiple regulatory functions
- Consulting SMEs that support clients with requirements-based solutions aligned with industry best practices
- Proven client expertise gained from regulatory experience at top global pharmaceutical companies
- Deep technical expertise on Veeva, OpenText, and the Amplexor Life Sciences Suite that has been acquired within the scope of strategic partnerships

Services

- Loading of content from clinical source systems
- Loading of content from source systems for submission
- Authoring of submission documents
- Conversion of document templates
- Preparation for submission readiness
- Migration of submission archives



Submission Management Expertise

Regulatory domain expertise	Markets
Publishing	USA, EU, GCC, ASEAN, ROW
CMC dossier compilation (annual reports, renewals, M1 to M5)	USA, EU, ROW
Labeling	EU (CP, MR, DCP)
Writing of protocols	USA, EU, Brazil, Australia

Key Benefits

- Global support from our team of certified onshore and offshore Calyx (formerly Liquent Insight) publishers
- Submission authoring and publishing experience in CMC, ROW, and MOW projects
- Familiarity with business processes and governance documentation related to submission management at global pharmaceutical companies
- Years of experience in regulatory information management (RIM) and migration of submission authoring and archive data

About CGI

Insights you can act on

Founded in 1976, CGI is now one of the world's largest IT and business consulting services firms.

We are insights-driven and outcomes-based to help accelerate the returns on your investments. Across hundreds of locations worldwide, we provide comprehensive, scalable and sustainable IT and business consulting services that are informed globally and delivered locally.

For more information

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